REMARKS

I. Status of the Claims

Claim 1 is amended.

Claims 1-3, 17-19, 21 and 22 are pending.

II. Only Rejections under 35 U.C.S. § 112 Remain

Amendments are supported in the specification at least in the following cites:

Page	Lines	Comments
2	8-12	target proteins
	20-28	non-target proteins
3	1	non-target proteins (the "comparative proteins")
	23-26	"Non-target proteins are selected for comparative purposes, by scanning for all available sequence matches in computer data bank. Amino acid sequences of at least 4 in length are selected from at least one of the protein sequences that showed some degree of homology to the target protein. Closest matches are preferred."
5	9-11	selection of "target proteins"
	13-18	use of computer programs such as BLAST to compare candidate peptide sequences to amino acid sequences in individual non-target (non-specific) proteins.
	28-29	compared to "proteins from non-target microorganisms or proteins from non-target tissues"
6	8-10	(same)
10	Fig. 2A	Comparison of peptide regions
11	1-5	BLAST cite
	Fig. 4	note the peptide did **not** satisfy the claimed criteria
12	Fig. 5	note the peptide did **not** satisfy the claimed criteria
	29-36	use of BLAST to compare candidate peptides with non-target peptides (those of skill would access the routine in BLAST for "short, nearly exact matches to the target protein")
13	1-14	These results would be inspected to select comparative protein specimens, as illustrated in the FIGS. Only candidate peptides satisfying all criteria claimed, would be employed in assays or in therapeutic regimes.
14	27-28	"Candidate peptides selected by algorithms of the present invention must be confirmed as specific immunogens." (see pp. 15-19, 1-6 Materials and Methods)

Those of skill in the art would access the routine in BLAST for "short, nearly exact

There is no paradox as the examiner states on page 5 of the Action. Those of skill in the art would have no trouble understanding what characteristics convert a "candidate peptide" to a "target peptide" capable of detecting an organism's response to a target protein from a microorganism, tissue and the like. (see Exhibit A)

The examiner misspoke when he argues that SEQ ID NO: 14 (FIG. 6) and SEQ ID NO: 21 are set forth as satisfying the criteria of claim 1 (d-f). Because (f) is the crucial criterion that the peptide of claim 1 elicits an immune response specific for the target protein, BLAST alone, as the examiner used, cannot provide information regarding (f).

Re peptides with SEQ ID NOS: 14 and 21 (FIG. 6) from target protein *H. pylori* when the statement was made "antigens, which satisfy all the criteria of the present invention", claim 1 that defined the invention was "at least four to about one hundred amino acids in length". Now claim 1(a) requires 5-10 amino acids, SEQ ID NO: 14 has 15 amino acids, so no longer satisfies claim 1(a) (nor does SEQ ID NO: 3).

Moreover, KNLESYQKDA is stated in FIG. 4 to not serve to identify *H. pylori* infected individuals . . . in spite of satisfying most of the selected criteria of the described invention, **thus confirming the need to test specific functional (immunogenic) of the peptide antigen.**" (*emphasis provided*)

The examiner further states that a "contiguous portion" YQKDA (more than 3)" is found to be homologous to many proteins. Of course - that is why SEQ ID NO: 6 would not work. Element 1(f) must be satisfied. Matches of linear amino acid sequences in a data base do not rule out a candidate peptide if the matched peptide still elicits a unique immunogenic response.

On pages 6, 8-9 of the Action, the examiner flounts well-established patent case law and Patent Office guidelines that indicates that patentability does not require demonstration of clinical success. Working examples are not required. The patent allows the inventor to assess the regulatory and commercial areas to find out if the invention is valuable. Dr. Anderson has already testified that one of skill in the art would find the invention credible and would know how to use it. By what authority does the examiner contradict this assertion and case law and substitute a personal opinion.

The examiner continues to fail considering the invention as a whole and continues to try to attack individual elements of the claims.

Regarding [0067] the illustrative comment is "at least 2" non-target proteins. There is no requirement made in case law to explain the inventor's guidance.

The presence of inoperative embodiments with the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which

embodiments that were conceived, but not yet made, would be inoperative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984).

A specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re *Borkowski*, 57 C.C.P.A. 946, 950 (C.C.P.A 1970).

An applicant need not have actually reduced the invention to practice prior to filing. The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. *In Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987).

III. Conclusion and Summary

In view of the arguments presented herein, please allow all pending claims. Applicant requests an interview.

No fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21417/92378).

Respectfully submitted,

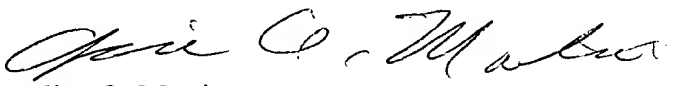

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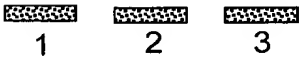
EXHIBIT A

Target Protein

Scan/screen using computer analysis to identify peptide regions with hydrophilic structure



Candidate Target Peptides (5-10 aa)

Compare the amino acid sequences of the candidate target peptides against a database that has a plurality of non-target proteins, *e.g.*, SwissProt or any other database. Computer algorithms are available to perform "near exact match" comparison.

Non-target Proteins

All six amino acids of the candidate target peptide match a part of the non-target protein (6/6—100%); not selected.

Only 3 amino acids of the candidate target peptide match a part of the non-target protein (3/6—50%); no more than 3 contiguous matches; selected.

Antigenic profile determined by immunogenic proliferation assays

Immunogenic Target Peptide